UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Carpenters and Joiners Welfare Fund, Universal Care Inc., Nancy Gerdts individually and for minor A.G., Cindy Slavens individually and for minor J.S., Alan and Laurissa Chilson, Leigh Ann Engh, Darcene and Greg Lensing, and on behalf of themselves and all others similarly situated,	)	Case No. CV 04-3500 MJD/SRN
Plaintiffs,	)	**SECOND AMENDED CLASS ACTION COMPLAINT**
v.	)	
SMITHKLINE BEECHAM CORPORATION d.b.a. GLAXOSMITHKLINE and GLAXOSMITHKLINE plc,	)	**JURY TRIAL DEMANDED**
Defendants.	)	

I. INTRODUCTION

1. Plaintiffs bring this action, pursuant to Rule 23 of the Federal Rules of Civil Procedure, individually and as representatives of a class of individuals consisting of all persons or entities who purchased and/or paid for the drug paroxetine (Paxil® or Paxil CR) from Defendant for consumption by a minor after November 19, 1998 including entities who paid for prescriptions on behalf of the purchaser or reimbursed the purchaser for the cost of the prescription.

2. Defendants have misrepresented information concerning the safety and efficacy of paroxetine for treating pediatric depression. Defendants have allowed positive information about pediatric use of paroxetine to be disclosed publically, but have withheld and concealed negative

information concerning the safety and effectiveness of the drug as a treatment for pediatric depression. Thus, Defendants have prevented physicians and their patients from properly and independently exercising their judgment regarding the use of paroxetine.

3. Plaintiffs bring this action individually and as class representatives to recover damages, restitution, refunds, and/or for equitable, injunctive and declaratory relief against Defendants for monies paid to purchase Paxil as a result of Defendant's wrongful conduct in connection with the marketing, distribution, testing, promotion, labeling and/or selling of paroxetine in the United States under the trade-names Paxil® and Paxil CR, in Europe under the trade-name and Seroxat. Plaintiffs seek to disgorge Defendants of the monies wrongfully acquired by it as a result its marketing and sale of Paxil.

II. PARTIES

4. Plaintiff Nancy Gerdts is a resident and citizen of the State of Minnesota, residing in Hopkins, Minnesota. Nancy Gerdts is the parent and legal guardian of A.G., a minor. Nancy Gerdts purchased, and A.G. began ingesting Paxil on or about August of 2002, when he was treating with a medical doctor for depressive symptoms. A.G. was 12 years old at the time of his first Paxil prescription.

5. Plaintiff Cindy Slavens is a resident and citizen of the State of Ohio, residing in Salem, Ohio. Cindy Slavens is the parent and legal guardian of J.S., a minor. Cindy Slavens purchased, and J.S. began ingesting, Paxil on or about March of 2000 when he was treating with a medical doctor for depressive symptoms. J.S. was 8 years old at the time of his first Paxil prescription.

6. Plaintiffs Alan Chilson and Laurissa Chilson are residents of the State of Minnesota,

residing in Stewartville, Minnesota. Alan Chilson was the legal guardian of Laurissa Chilson during the time of her minority. Alan Chilson purchased, and Laurissa Chilson was prescribed and began ingesting, Paxil on or about July of 2000 when he was treating with a medical doctor for depressive symptoms. Laurissa Chilson was 15 years old at the time of her first Paxil prescription.

7. Plaintiff Leigh Ann Engh is a resident of the State of Indiana. Plaintiff Engh purchased Paxil on her daughter's behalf.

8. Plaintiffs Darcene and Greg Lensing are residents of Comfrey, Minnesota. Plaintiffs Darcene and Greg Lensing purchased Paxil on their daughter's behalf.

9. Plaintiff Universal Care Inc. ("UCI") is incorporated under the laws of the State of California.

10. UCI is a health insurer who paid, in whole or in part, for paroxetine that a number of its insured policyholders obtained on behalf of their minor children.

11. The Carpenters & Joiners Welfare Fund is a multi-employer jointly-trusteed fringe benefit plan created and maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act of 1947 ("LMRA"), as amended 29 U.S.C. § 186(c)(5). The Fund is administered in accordance with the provisions of the Employee Retirement Income Security Act of 1974, as amended 29 U.S.C. § 1001, et seq. ("ERISA"), and is exempt from federal income taxation pursuant to Internal Revenue Code Section 501(c)(9). The Carpenters & Joiners Welfare Fund is administered in Hennepin County, Minnesota with its address being 3001 Metro Drive, Suite 500, Bloomington, MN 55425.

12. Plaintiff Carpenters & Joiners Welfare Fund reimbursed its members for Paxil purchased for use by minors.

13. Defendant GlaxoSmithKline plc is a public limited liability company incorporated in England and Wales and headquartered in the United Kingdom at Glaxo Welcome House, Berkely Avenue, Greenford, Middlesex, England. In December 2000, GlaxoSmithKline plc acquired British companies Glaxo Wellcome plc and SmithKline Beecham plc. Through several levels of wholly owned subsidiaries, GlaxoSmithKline owns SmithKline Beecham Corporation d/b/a GlaxoSmithKline, which was engaged in the business of marketing and distributing paroxetine under the trade names Paxil and Paxil CR (hereinafter "Paxil").

14. SmithKline Beecham Corporation is a Pennsylvania corporation, with its principal place of business located at One Franklin Plaza, Philadelphia, Pennsylvania. SmithKlineBeecham Corporation does business as GlaxoSmithKline, and is owned, through several levels of wholly owned subsidiaries, by GlaxoSmithKline plc.

15. GlaxoSmithKline plc and SmithKline Beecham Corporation d/b/a GlaxoSmithKline will hereinafter be referred to collectively as "GSK" or Defendants.

16. At all times relevant to the matters alleged in this Complaint, each Defendant acted as the agent of the other Defendant, within the course and scope of such agency, regarding the acts and omissions alleged.

17. At all times relevant, Defendants sold, promoted and distributed Paxil and Paxil CR throughout the United States.

III. JURISDICTION AND VENUE

18. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 (a) because there is complete diversity of citizenship between Plaintiffs and Defendants, and because the amount in controversy exceeds $75,000, exclusive of interest and costs. Additionally, supplemental

jurisdiction exists pursuant to 28 U.S.C. § 1367 in that the claims of all parties and class members are so related they form part of the same case or controversy.

19. Venue is properly laid in this District pursuant to 28 § U.S.C. 1391. Paxil prescriptions were written in the District of Minnesota and Defendants advertised in this District and made material omissions and misrepresentations in this District.

IV. CLASS ACTION ALLEGATIONS

20. Plaintiffs bring this action, pursuant to Rule 23 of the Federal Rules of Civil Procedure, on their own behalf and as representatives of the following class:

> All persons or entities who purchased and/or paid for the drug paroxetine (Paxil® or Paxil CR) from GSK for consumption by a minor after November 19, 1998 including entities who paid for prescriptions on behalf of the purchaser or reimbursed the purchaser for the cost of the prescription.

21. Plaintiffs seek a refund of all amounts paid by Members of the Class for purchases of Paxil from GSK.

22. The Class includes thousands of entities and others who purchased and/or paid for Paxil for consumption by a minor and, therefore, the members of the Class are so numerous that joinder is impracticable.

23. There are questions of law and fact common to the Class including, but not limited to, the following:

a. whether Defendants misrepresented the intended and approved uses of Paxil by providing false or misleading information about the clinical evidence relating to the efficacy and safety of paroxetine;

b. whether Defendants negligently, recklessly or intentionally concealed the

negative clinical information about paroxetine from Plaintiff and members of the Class;

c. whether Defendants negligently, recklessly or intentionally made false statements to physicians and pharmacists concerning the efficacy and safety of paroxetine for off-label uses;

d. whether Defendants acted negligently at the expense of Plaintiffs and members of the Class;

e. whether Defendants' conduct has resulted in unjust enrichment at the expense of the Plaintiffs and members of the Class;

f. whether Defendants' conduct has resulted in a breach of implied warranties;

g. whether Defendants' conduct constitutes fraudulent concealment;

h. whether Plaintiffs and members of the Class are entitled to a refund of all amounts paid for their purchases of Paxil;

i. whether Plaintiffs and members of the Class are entitled to damages and other equitable relief; and

j. whether Plaintiffs and members of the Class are entitled to attorneys fees.

24. The above-identified questions of law and/or fact are common to the Class and predominate over questions, if any, affecting only individual class members.

25. The claims of the named Plaintiffs are typical of the claims of the Class they seek to represent.

26. Plaintiffs and members of the proposed Class seek a refund of and reimbursement for monies paid for their purchases of Paxil, all of which occurred as a result of Defendants'

wrongful and improper conduct in connection with the marketing, distribution, testing, promotion, labeling and/or selling of paroxetine for the treatment of pediatric depression. Plaintiffs and members of the proposed Class seek to disgorge defendants of the monies wrongfully acquired by it as a result of its sale of Paxil for the treatment of pediatric depression.

27. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the necessary duplication of evidence, effort, and expense that numerous individual actions would require.

28. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Plaintiffs have retained counsel competent and experienced in complex class actions and products liability litigation to represent them. Accordingly, the interests of the Class will be adequately protected and advanced.

29. Class certification pursuant to Federal Rule of Civil Procedure 23(b)(1) is appropriate because separate actions by individual members of the Class would create a risk of inconsistent adjudications which could establish incompatible standards of conduct for Defendant.

30. Class certification pursuant to Federal Rule of Civil Procedure 23(b)(3) is appropriate because the class action is superior to all other available methods for the fair and efficient adjudication of this controversy, and the questions of law or fact common to the members of the Class predominate over any questions affecting only individual Class members.

31. The damages suffered by individual Class members are small compared to the

burden and expense of individual prosecution of the litigation needed to address Defendants' conduct. Furthermore, it would be virtually impossible for the members of the Class individually to redress the wrongs that they have individually suffered. Even if Class members themselves could afford such individual litigation, the court system could not, given the size of the class. In addition, individualized litigation increases the delay and expense to all parties and to the court system. Individualized litigation also presents a potential for inconsistent or contradictory judgments. By contrast, class action litigation presents far fewer management difficulties, allows adjudication of claims that might otherwise go unaddressed because of the expense of bringing individual litigation, and provides the benefits of uniform adjudication, economies of scale, and comprehensive supervision by a single court.

32. Notice can be provided to class members by a combination of published notice and first class mail using techniques and forms of notice similar to those customarily used in complex class actions involving drug-related product liability claims.

V. FACTUAL ALLEGATIONS

Off-Label Use

33. The FDA approves drugs for use based upon whether they are safe and effective as determined through scientifically conducted clinical studies. Efficacy is assessed by whether the drug is superior to placebo and whether that superiority is statistically significant, (i.e., the difference in the outcome cannot be explained by chance alone). To provide solid evidence of a drug's efficacy, and therefore its benefit to patients, a study should be randomized, placebo-controlled and double-blind.

34. The FDA approves a drug for specific conditions or diseases and for specific

populations, such as patients under the age of 18 years ("pediatric population") or adults.

35. The FDA has approved Paxil as safe and effective in treating various indications in adults, but not for any illness or condition in the pediatric population.

36. Physicians may prescribe a drug for conditions or diseases for which FDA approval has not been obtained when, in the physician's professional judgment, it is an appropriate treatment for the individual patient and the drug has already been approved by the FDA for some other use.

37. A physician's judgment is based upon the balance between (a) the benefit the patient is likely to derive from the treatment, including the harm or benefit, if any, of providing no treatment or an alternative treatment, and (b) the risk that the proposed treatment will cause the patient harm, and the nature and severity of that harm.

38. In deciding whether to prescribe a drug for an off-label use, physicians typically rely upon their assessment of information received from other sources. Such information must be accurate and provide an unbiased picture of a drug's safety and efficacy in treating a condition. If the information is false or misleading, the physician cannot accurately assess the crucial risk-benefit balance for the patient or properly exercise her judgment.

39. Concealing or providing inaccurate or biased information that is material to a prescribing decision misleads the physician and the patient who relies on that physician's judgment.

40. Purchases made by Plaintiffs and the Class members were "off-label", and the sale of Paxil to the Class members was not made for an FDA approved use.

Paxil Efficacy and Safety Studies

41. GSK conducted three multi-center, placebo-controlled, double-blind clinical studies to assess the safety and efficacy of paroxetine in treating children and adolescents diagnosed with

major depressive disorder ("MDD"). These studies are referred to by GSK as Studies 329, 377 and 701.

42. GSK management received the final clinical reports for Studies 329 and 377 in November of 1998 and for Study 701 on July 31, 2001.

43. Studies 329, 377 and 701 were multi-center, double-blind, placebo controlled, parallel group trials of the efficacy and safety of treatment with paroxetine in children (Study 701) and adolescents (Studies 329, 377 and 701).

44. GSK conducted two additional studies that were extensions of Studies 329 and 701. The extension of Study 329 (final clinical report approved by GSK on October 31, 2001), which included only pediatric patients with MDD, was not randomized. It was designed to evaluate relapse rates and long-term safety - not efficacy. Study 716 (final clinical report approved by GSK on September 16, 2002), was not randomized, placebo-controlled or blind. All participants in Study 716 received paroxetine during the extension, and included participants from completed studies of pediatric patients with MDD (Study 701) or Obsessive Compulsive Disorder ("OCD"). It examined the longer-term safety of paroxetine.

45. Two of the three GSK placebo-controlled Studies (377 and 701) failed to show that paroxetine was more effective than placebo, or that there was any evidence of efficacy for treating MDD in children and adolescents.

46. Study 329 (issue date November 24, 1998), a multi-center, double-blind, placebo controlled, parallel group trial of the efficacy and safety of treatment of adolescents with paroxetine presented a mixed picture of efficacy. Before Study 329 began, GSK specified seven measures of efficacy, two of which it identified as "primary" and five it identified as "secondary". The efficacy

of paroxetine was not measured as superior to placebo at a level of statistical significance on either of the primary measures. Only three of the five secondary measures found paroxetine to be superior to placebo.

47. Study 377 (issue date November 19, 1998), a multi-center, double-blind, randomized, parallel group, placebo controlled study of the efficacy and safety of paroxetine in adolescents, found that "[n]o clinically or statistically significant differences were detected between paroxetine and placebo in either of the [two] primary efficacy variables," nor on any of the secondary measures. The synopsis of Study 377 concluded "The results failed to show any superiority for paroxetine over placebo in the treatment of adolescent depression".

48. In Study 701 (issue date July 30, 2001), a multicenter, randomized, double-blind, placebo-controlled, parallel-group, flexible-dose trial in children and adolescents, placebo actually outperformed paroxetine on the primary efficacy measure, and no statistically significant differences were found between paroxetine and placebo on any of the secondary measures.

49. GSK's studies also showed an increased rate of adverse events, including increased suicidal ideation and increased hostility as compared to placebo.

50. The Medicines and Healthcare products Regulatory Agency in the United Kingdom ("MHRA") commented on the "Safety Profile" of Paroxetine, as shown in the GSK studies, to be "Increased rate of self-harm and suicidal thoughts compared with placebo."

Selective Publication

51. GSK limited physicians' access to only the most favorable aspects of the data from these studies by failing to disclose the negative information concerning the drug, by manipulating the dissemination of the study data, and by misrepresenting the results of the studies it had

conducted concerning the drug's efficacy and safety in the pediatric population.

52. GSK sought publication of the results of Study 329 (the one with mixed results) and did not submit the results of Studies 377 and 701 (the failed studies that showed no efficacy), and did not publish the results of extension studies which raised additional safety concerns.

53. An internal GSK document from October of 1998 discussed the results of GSK "clinical trials designed to assess the efficacy and safety of Seroxat/Paxil in adolescents with major depression." The GSK internal document concluded that Seroxat/Paxil "failed to demonstrate a statistically significant difference from placebo on the primary efficacy measures" in Study 329 and "failed demonstrate any separation of Seroxat/Paxil from placebo" on Study 377.

54. According to the document, GSK's "TARGET" was "To effectively manage the dissemination of these data in order to minimise any potential negative commercial impact."

55. As part of its campaign to "manage the dissemination of these data," the document recommended that GSK prepare and cause the publication of a full article on Study 329 - the only study with some favorable conclusions, and indicated GSK had no plans to publish data from Study 377.

56. The internal GSK memo also states that the data from Studies 329 and 377 were "insufficiently robust to support a label change and will therefore not be submitted to the regulatory authorities."

57. The memo elaborates on the plan regarding what information would be provided to regulators, stating that "[b]ased on the current data from Studies 377 and 329... no regulatory submissions will be made to obtain either efficacy or safety statements relating to adolescent depression at this time. However, data (especially safety data) from these studies may be included

in any future regulatory submissions, provided that we are able to go on and generate robust, approvable efficacy data."

58. The GSK internal document states "it would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of paroxetine."

59. Thereafter, and in accordance with the recommended plan, the "positive data" from Study 329 was presented in abstract form in November of 1998, and an article that described and analyzed the results of Study 329 was subsequently published in a professional journal. The authors of this article included two GSK employees.

60. Although it allowed the data from Study 329 to be published, GSK chose not to seek publication of Studies 377 and 701 which failed to show that paroxetine was more effective than placebo in treating pediatric depression.

61. Neither Study 377 nor Study 701 has ever been published, nor were the results of the extension phase of Study 329 and Study 716, and they remained unavailable to the general public until being posted on the GlaxoSmithKline website in the early summer of 2004.

62. The data in Studies 377 and 701, as well as the data from the extension phase of Study 329 and Study 716, are material to Paxil's risk-benefit analysis and, therefore, to a physician's decision whether to prescribe paroxetine to a child or adolescent. This is especially true in light of the publication of Study 329 and the misrepresentation of the overall clinical data.

63. In 1997, Congress passed a provision allowing manufacturers of drugs licensed for sale in the adult population (which enjoy exclusive patent rights to market their drugs), to obtain six additional months of patent exclusivity (for all age groups) by conducting a study on safety and

efficacy for pediatric use of their drug and submitting it to the FDA. This is commonly known as "Pediatric Exclusivity".

64. The FDA and the Department of Health and Human Services wrote in the summary of the final rule that "product labeling frequently fails to provide directions for safe and effective use in pediatric patients. This rule will partially address the lack of pediatric use information by requiring that manufacturers of certain products provide sufficient data and information to support directions for pediatric use for the claimed indications."

65. Almost four years after completing initial Studies 329 and 377, Studies 329 and 377 along with Study 701 and several other studies relating to Paxil in other subclasses of patients were submitted by GSK to obtain the benefit of Pediatric Exclusivity and the six-month patent extension for all users of Paxil.

66. After completing its clinical review of GSK's Pediatric Exclusivity submission (dated 10-7-02), the FDA concluded that Study 377 "did not provide any evidence that paroxetine is active in the treatment of adolescent MDD, that Study 701 "did not provide any evidence that paroxetine is effective in the treatment of pediatric MDD", that Study 329 "should be considered as a failed trial, in that neither active treatment group showed superiority over placebo by a statistically significant margin."

67. The Pediatric Exclusivity benefit was not dependent on the result of the submitted studies - just the submission of pediatric studies regardless of outcome.

68. GSK was granted the Pediatric Exclusivity six-month patient extension applicable to all United States sales of Paxil in June of 2002.

69. In February 2004, the FDA its one year post exclusivity adverse event review as

mandated by the Best Pharmaceuticals for Children Act on Paxil. The adverse events known to GSK and included in the report include nine completed suicides, seventeen suicide attempts, and four completed homicides.

70. GSK took no steps to inform the medical community or the public of the failed studies, the FDA's conclusions, or other adverse events.

71. GSK took no action to request any labeling changes to make physicians and consumers aware of the failed studies, the FDA conclusion that the studies were all failed, or of the serious adverse events associated with pediatric use of Paxil.

72. Upon information and belief, during the six month patent extension, GSK made hundreds of millions of dollars in profit from the exclusive marketing of Paxil.

GSK Misrepresented Efficacy of Paxil

73. Despite the negative information contained in Studies 377 and 701, GSK repeatedly misrepresented and fostered a false impression that Paxil was safe and effective for the treatment of depression in the pediatric population.

74. In an internal cover memo to its sales representatives, GSK stated that "Paxil demonstrates REMARKABLE Efficacy and Safety in the treatment of adolescent depression."

75. Upon information and belief, a GSK internal newsletter quoted one of the doctors who authored the article on Study 329 indicating that paroxetine has both efficacy and safety data for the treatment of depression in adolescents.

76. As of November 2001, GSK had completed and approved the final clinical reports on Studies 329, 377 and 701, and the extension phase of Study 329. GSK issued Medical Information Letters both of which materially omitted the negative information known to GSK

concerning the safety and efficacy of paroxetine for treating MDD in children and adolescents. GSK enclosed the published article concerning Study 329 with some of its Medical Information Letters.

77. Study 377 failed to show efficacy for any of the measured outcomes. GSK manipulated the information disclosed in the Medical Information Letters by indicating that one outcome was numerically superior to placebo but not statistically significant. The Medical Information Letters failed to communicate GSK's own conclusion that there was no clinical significance, as well as no statistical significance, in the outcomes from Study 377. Nor did these Medical Information Letters include any reference to Study 701 in which placebo outperformed paroxetine. Each of these Medical Information Letters, however, reported open label (non-placebo-controlled) studies with positive efficacy results.

78. In 2002, GSK finally submitted to the FDA the final clinical reports for Studies 329, 377 and 701, which assessed the safety and efficacy of paroxetine in the treatment of MDD in pediatric patients. GSK subsequently provided these materials to the drug-regulatory agencies of other countries.

79. Upon information and belief, in response to safety and risk-benefit issues raised by the MHRA and the European Agency for the Evaluation of Medicinal Products ("EMEA"), GSK admitted that Studies 329, 377 and 701 "all failed to separate paroxetine from placebo overall and so do not provide strong evidence of efficacy in this indication."

80. On June 10, 2003, the MHRA stated that its analyses of GSK's studies suggested the risk of self-harm and potential suicidal behavior of youngsters with MDD was between 1.5 and 3.2 times greater for the paroxetine group than for the placebo group. The MHRA reported that its Committee on Safety of Medicines advised that paroxetine "should not be used in children and

adolescents under the age of 18 years to treat depressive illness." The agency also added "pediatric status" as a contraindication on the paroxetine labeling in the UK. The Irish Medicines Board adopted a similar pediatric contraindication in December 2003.

81. In response to the MHRA's June 10, 2003 warning, GSK admitted in a letter to physicians in the UK that the "clinical trials in children and adolescents under 18 years of age failed to demonstrate efficacy in Major Depressive Disorder, and that there was a doubling of the rate of reporting of adverse events in the paroxetine group compared with placebo, including ... emotional liability." GSK further stated that paroxetine was indicated for use in children under the age of 18 and "controlled clinical studies failed to demonstrate efficacy and do not support the use of Seroxat [paroxetine] in the treatment of children with Major Depressive Disorder."

82. On June 19, 2003, the FDA issued a Talk Paper stating that it was reviewing data from studies of paroxetine use in children and adolescents with MDD to assess a possible increased risk of suicidal thinking and attempts in this population. Noting the absence of evidence supporting efficacy of Paxil, and acknowledging that its review of the safety data was not complete, the FDA recommended "that Paxil not be used in children and adolescents for the treatment of MDD." In a second Talk Paper issued in October 2003, the FDA did not retract its finding that three "well-controlled" clinical trials of paroxetine did not establish its efficacy in treating MDD in the pediatric population. Instead, it noted the scientific fact that the lack of evidence of efficacy in any *"particular"* study is not *"definitive"* evidence that the drug is not effective. (emphasis added.) The FDA also acknowledged that a possible link between paroxetine and an increased risk of suicidal thoughts and acts was under agency review, and advised that paroxetine and other Selective Serotonin Reuptake Inhibitors or ("SSRI") drugs be used with caution. The FDA strengthened its

advice to use SSRIs with caution in a third Talk Paper issued on March 22, 2004.

83. In July of 2003, following discussions with Health Canada, GSK issued a Dear Health Care Professional Letter intended for physicians in Canada. The letter stated that "until further information is available Paxil® (paroxetine hydrochloride) should not be used in children and adolescents under 18 years of age." The letter noted that "there is new evidence from three pediatric placebo-controlled trials in MDD of an increased risk of suicidal thinking, suicide attempts or self harm." This "new" evidence had been available to GSK since November 1998.

84. The July 2003 Canadian Dear Health Care Professional letter admitted that "[i]n pediatric patients with Major Depressive Disorder (MDD), Paxil® is *contraindicated*, due to additional evidence of lack of efficacy." The letter explained that "[t]he three trials also demonstrated that Paxil® failed to show greater efficacy than placebo in MDD" and advised that "Paxil® should not be prescribed as new therapy for patients under 18 years of age."

85. Subsequently, GSK changed the Canadian Paxil label to read: "The use of Paxil® in children under 18 years of age is not recommended as safety and efficacy have not been established in this population."

86. Despite its 2003 admissions to regulatory agencies and to the public in other countries, regulatory authorities' negative assessment of efficacy and articulated safety concerns about the use of paroxetine by children and adolescents with MDD, and the Canadian label change disclosing that paroxetine was not indicated for pediatric use, GSK continued to misrepresent and foster a false impression in the United States about the efficacy of Paxil in treating pediatric depression in an ongoing effort to remain in the pediatric market.

87. While GSK admitted there was no evidence of efficacy for Paxil in the treatment of

pediatric depression, GSK did not provide this information to health care providers in the United States nor did it inform the public of this fact by making a label change to reflect their clinical findings from 1998 and 2001.

88. In 2003, in response to FDA concerns raised in the Talk Papers, GSK began to admit in their Medical Information Letters that efficacy "was not shown for MDD". Yet GSK did not disclose the fact that paroxetine had failed its efficacy studies or that it had already admitted this lack of efficacy to European and Canadian regulatory authorities and that it had made label changes in those countries admitting paroxetine was not indicated for the treatment of pediatric depression.

89. GSK further controlled physicians' access to negative information about paroxetine as a treatment for pediatric MDD by controlling the information provided to its own personnel and, therefore, the information used in promoting the drug to prescribing physicians. By highlighting Study 329 and not disclosing the negative studies and data, GSK successfully created a false impression that Paxil was a safe and effective treatment for pediatric depression.

90. GSK admitted paroxetine's lack of efficacy in response to regulatory inquiries in Europe and Canada but, at the same time, failed to provide Americans with this same information. Instead, GSK disclosed only as much information as necessary, and did so by sending out Medical Information Letters only to those physicians who specifically requested them. By omitting the critical negative information concerning paroxetine as a treatment for depression in children and adolescents, GSK was able maintain its market share and continue selling the drug to pediatric patients for an off-label us it knew to be contraindicated.

91. GSK perpetuated the misrepresentation by omitting material facts known to it since

1998 in its labeling of Paxil in the United States. The U.S. label for Paxil did not reflect that Paxil failed to demonstrate efficacy and was contraindicated for pediatric depression following the failed 1998 studies. Even after admitting that the clinical trials failed to show efficacy in Europe and Canada, and actually making label changes in those markets, GSK did not change the U.S. label to provide adequate and full disclosure of this critical information.

92. GSK took affirmative steps to manipulate what information was disclosed in order to keep negative information about the pediatric use of paroxetine from the American public. Unlike GSK's June 10, 2003 press release in Britain, which admitted that GSK had "seen a difference between [paroxetine] and placebo in terms of suicidal thinking or attempts [in its MDD studies]; particularly in adolescents," GSK's June 19, 2003 American press release noted only that "there is no evidence that Paxil is associated with an increased risk of suicidal thinking or acts in adults" and that "not a single person [who participated in the pediatric paroxetine trials] committed suicide." The American press release provided no efficacy information material to treatment decisions for pediatric patients with depression, despite their knowledge of the failed efficacy studies.

93. GSK's failure to promptly disclose the findings of Studies 377 and 701, and the safety outcomes of Studies 329-extension phase and 716, created the false impression that, based upon the scientific evidence in GSK's control, paroxetine was safe an effective for treating depression in children and adolescents and, therefore, that the risk-benefit balance was well settled and generally favorable for this off-label use. This impression was reinforced by GSK's mischaracterization of much of the information it did disclose, its further concealment and suppression of negative information, and its misleading marketing of the drug as safe and effective for the treatment of pediatric depression.

94. GSK misled and deceived physicians and, consequently, the patients who relied upon their professional judgment. GSK deprived physicians of the information needed to evaluate the risks and benefits of prescribing paroxetine for their pediatric patients with MDD.

95. In June 2004, the FDA wrote to GSK informing them that a television ad campaign, where actors in vignettes appeared with name-tags reading *nervous, self-conscious, anxious* and *afraid,* was "false or misleading because it contains a representation or suggestion, not approved or permitted for use in the labeling, that Paxil CR is useful in a broader range of conditions or patients, and is safer than has been demonstrated by substantial evidence or substantiated clinicial experience..." Similarly, GSK has and continues to misrepresent the efficacy of Paxil and Paxil CR for treatment of pediatric depression. The official Paxil website, owned and maintained by GSK, contains images of young females who appear to be adolescents, notably appearing (for example) on a page accessed by clicking on the "LEARN ABOUT USES" tab, and then clicking on the "DEPRESSION" and "TREATMENT" tabs. This page shows the image of two young girls who appear to be adolescents. The title appearing on this page is "How is depression treated". This promotional material suggests that Paxil is appropriate for the population represented by those featured in the accompanying photo, when in fact GSK has admitted that Paxil is not recommended for use by children and adolescents. No warning, contraindication, or disclaimer is offered to counter this misleading suggestion.

When All The data Is Reviewed Paroxetine (Paxil) Shows No Efficacy For The Treatment Of Depression In Children And Adolescents

96. On April 22, 2004, following its review of all GSK paroxetine trials, the Committee for Proprietary Medicinal Products of the EMEA announced its recommendation to the European

Commisson that paroxetine not be prescribed for pediatric patients.

97. On April 24, 2004, *The Lancet* published a study entitled Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data, 363: 1341-45 (2004). The study was conducted due to "serious concerns about withholding unfavourable trial data and under-reporting of adverse events" and was intended to "investigate the risk-benefit profile of individual SSRIs using published data, unpublished data, and the combined dataset." *The Lancet* study found that "[p]ublished results from one trial of paroxetine ... suggest[s] equivocal or weak positive risk-benefit profiles; however ... [the] addition of unpublished data indicated that risks outweighed benefits." The study concluded that "[a]fter pooling all available data, evidence continued to suggest that paroxetine does not improve depressive symptoms" and "little evidence remained for efficacy."

98. In May of 2004, GSK responded to an FDA Public Health Advisory relating to the use of antidepressants with a "Dear Healthcare Professional" letter. In the May 2004 letter, GSK states that Paxil and Paxil CR are "not approved for use in the pediatric population, **and clinical trials for PAXIL failed to demonstrate efficacy in pediatric depression.**" (emphasis added). This admission comes five and one-half years after Study 377 failed to show efficacy, and three years after Study 701 failed to show efficacy in the treatment of pediatric depression. This admission is based on the very studies and that were available to and within GSK control since 1998. The May 2004 Dear HealthCare Professional Letter still omits the critical fact that paroxetine is **contraindicated** for pediatric depression, a fact admitted by GSK in Europe and Canada.

99. On September 9, 2004, Dr. David Wheadon, GlaxoSmithKline Vice-President of U.S. Regulatory Affairs, testified before a Congressional Investigation Panel on publication and

disclosure issues in anti-depressant pediatric clinical trials. At this hearing, GSK admitted "we certainly would and have indicated that the drug has not been shown to be effective."

100. GSK still has not changed its labeling for Paxil in the United States or otherwise informed American physicians and consumers of the critical information, known to GSK since 1998, that paroxetine failed to demonstrate efficacy in pediatric depression. GSK still has not changed its U.S. label or otherwise informed American physicians and consumers that Paxil is "not recommended" for pediatric depression as it has done elsewhere.

VI. PLAINTIFFS' CAUSES OF ACTION

COUNT I

FRAUD

99. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein, and further allege as follows:

100. As previously alleged with particularity in this Complaint, each of these representations by GSK was false, material to the marketability and commercial value of Paxil, and were intended by GSK to induce and mislead physicians to prescribe Paxil, Plaintiffs and Class Members to purchase Paxil, and Plaintiffs and Class Members to refrain from taking steps to seek alternative treatment options with a more favorable risk-benefit profile.

101. As alleged above, Defendants made representations known to be false, and with a reckless disregard for the truth, concerning the safety and efficacy of Paxil in the pediatric population.

102. Defendants knowingly omitted material facts concerning the safety and efficacy of Paxil from prescribing physicians, consumers, and the general public.

103. Defendants intended that individuals would rely on these material misrepresentations to the economic benefit of GSK.

104. In reasonable reliance upon these material misrepresentations of GSK, physicians were in fact induced to prescribe, and Plaintiffs and Class Members were induced to purchase Paxil.

105. These representations by GSK include, but are not limited to the following:

a. suppression and/or mischaracterization regarding the efficacy of Paxil in treating pediatric depression;

b. failing to timely and fully disclose the results of its studies concerning the safety and efficacy of Paxil in the treatment of pediatric depression; and

c. failing to disseminate adequate warnings and information concerning the safety and efficacy of Paxil in the treatment of pediatric depression.

106. As a direct and proximate consequence of Defendants' fraudulent misrepresentations, Plaintiffs and Class Members were damaged by: 1) failing to receive full value for their direct or indirect payment of money to GSK for a safe and effective prescription drug for the treatment of pediatric depression; 2) incurring personal debt and/or out-of-pocket expenditures to purchase Paxil; and 3) foregoing safe and effective alternative treatment options in reliance upon GSK's misrepresentations that Paxil was a safe and effective treatment for pediatric depression.

COUNT II

VIOLATION OF CONSUMER PROTECTION STATUTES

107. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein,

and further allege as follows:

108. As previously alleged with particularity in this Complaint, each of these representations by GSK was false, material to the marketability and commercial value of Paxil, and were intended by GSK to induce and mislead physicians to prescribe Paxil, Plaintiffs and Class Members to purchase Paxil, and Plaintiffs and Class Members to refrain from taking steps to seek alternative treatment options with a more favorable risk-benefit profile.

109. As alleged above, Defendants made representations known to be false, and with a reckless disregard for the truth, concerning the safety and efficacy of Paxil in the pediatric population.

110. Defendants knowingly omitted material facts concerning the safety and efficacy of Paxil from prescribing physicians, consumers, and the general public and Defendants intended that individuals would rely on these material misrepresentations to the economic benefit of GSK.

111. Minnesota, Pennsylvania and all other states and the District of Columbia have enacted statutes to protect consumers from these deceptive and fraudulent trade practices and Defendant violated these statutes by knowingly and falsely representing Paxil was fit to be used for the purpose for which they were intended, when Defendant knew it was ineffective, unsafe and by other acts alleged herein.

112. In reasonable reliance upon these material misrepresentations of GSK, physicians were in fact induced to prescribe, and Plaintiffs and Class Members were induced to purchase Paxil.

113. These representations by GSK include, but are not limited to the following:

a. suppression and/or mischaracterization regarding the efficacy of Paxil in treating pediatric depression;

b. failing to timely and fully disclose the results of its studies concerning the safety and efficacy of Paxil in the treatment of pediatric depression; and

c. failing to disseminate adequate warnings and information concerning the safety and efficacy of Paxil in the treatment of pediatric depression.

114. As a direct and proximate consequence of Defendants' fraudulent misrepresentations, Plaintiffs and Class Members were damaged by: 1) failing to receive full value for their direct or indirect payment of money to GSK for a safe and effective prescription drug for the treatment of pediatric depression; 2) incurring personal debt and/or out-of-pocket expenditures to purchase Paxil; and 3) foregoing safe and effective alternative treatment options in reliance upon GSK's misrepresentations that Paxil was a safe and effective treatment for pediatric depression.

COUNT III

MISREPRESENTATION

115. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein, and further allege as follows:

116. Defendant GSK fraudulently, negligently, falsely and/or deceptively represented or knowingly omitted, suppressed or concealed facts of such materiality regarding the safety and efficacy of Paxil.

117. Defendant GSK made assertions that were not in accord with the facts known to them at the time.

118. Defendant GSK remained silent and/or offered false information despite its

knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of Paxil, and did so because the prospect of huge profits, all to the significant detriment of plaintiffs and members of the class.

119. Defendant GSK was otherwise careless, fraudulent, negligent, grossly negligent, and acted with willful and wanton disregard for the rights of Plaintiffs and members of the class in the representations regarding the safety and efficacy of Paxil.

120. Defendant GSK failed to use reasonable care or competence in obtaining and communicating such information to Plaintiffs and members of the Class, and said information was, in fact, false.

121. The material misprepresentations and omissions of GSK were likely to induce a reasonable person to manifest their assent without being fully informed of all the facts.

122. Plaintiffs and members of the Class justifiably relied upon the information provided by GSK to their economic detriment.

COUNT IV

BREACH OF EXPRESS WARRANTIES

123. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

124. Defendants' expressly warranted through affirmation of fact that Paxil was an effective treatment for depression in the pediatric population.

125. Paxil did not conform to this express representation of the defendant because Paxil failed to show efficacy for treatment of adolescent depression in the clinical trials conducted by GSK.

126. As a direct and proximate result of the breach of said warranties, plaintiffs suffered economic loss as alleged herein.

COUNT V

BREACH OF IMPLIED WARRANTIES

127. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

128. At the time Defendants marketed, sold, and distributed Paxil for use by plaintiffs and class members, defendant knew of the use for which Paxil was intended, and impliedly warranted this drug to be of merchantable quality and safe and fit for such use.

129. Plaintiffs and their physicians reasonably relied upon the skill and judgment of defendant as to whether Paxil was of merchantable quality and safe and fit for its intended use.

130. Contrary to such implied warranty, Paxil was not of merchantable quality or safe or fit for its intended use, because the drug was not effective for the treatment of pediatric depression, and was therefore unfit for the ordinary purpose for which it was used as described above.

131. As a direct and proximate result of the breach of implied warranties, Plaintiffs and Class Members suffered economic loss as alleged herein.

COUNT VI

REFUND/RESTITUTION RELIEF

132. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein, and further allege as follows:

133. Plaintiffs, and each member of the entire Class, conferred a benefit upon the Defendants by purchasing Paxil for the treatment of pediatric depression.

134. This benefit was conferred as direct result of Defendants' fraud, misrepresentations, and breach of warranties.

135. As a direct and proximate result of the Defendants' acts, omissions and conduct as set forth above, Plaintiffs, and each Class member, are entitled to an award of a refund, reimbursement and incidental economic losses, including the purchase price paid by Class members in connection with their purchases of paroxetine, Paxil® or Paxil CR.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

1. Certification of this action as a class action on behalf of the proposed class of plaintiffs who have purchased or paid for paroxetine (Paxil or Paxil CR);

2. Refund and reimbursement of all monies for purchase of Paxil or Paxil CR and disgorgement of all profits acquired by means of the above practices and through the sales of Paxil® or Paxil CR to plaintiffs and members of the proposed Class;

3. Prejudgment and post judgment interest as provided by law;

4. Attorney's fees, expenses, and costs of this action; and

5. Such further relief as this court deems necessary, just and proper.

Dated: 5.1.08

MESHBESHER & SPENCE, LTD.

By _____

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